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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-----------------------|---------------------|------------------|
| 09/919,025   | 07/31/2001  | Neill B. Walsdorf SR. | HO-P02490US0        | 3707             |
| 26271  | 7590        | 09/22/2004            | EXAMINER            |                  |
| FULBRIGHT & JAWORSKI, LLP<br>1301 MCKINNEY<br>SUITE 5100<br>HOUSTON, TX 77010-3095 |             |                       | CHOI, FRANK I       |                  |
|  |             |                       | ART UNIT            | PAPER NUMBER     |
|  |             |                       | 1616                |                  |

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/919,025 | <b>Applicant(s)</b><br>WALSDORF ET AL. |  |
|                              | <b>Examiner</b><br>Frank I Choi      | <b>Art Unit</b><br>1616                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 6/23/2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-12, 15-17, 21-24 and 29-31 is/are allowed.
- 6) ☒ Claim(s) 13, 14, 18-20, 25-28 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

#### *Claim Rejections - 35 USC § 102/103*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13,14,18-20,25-28,32 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over CN 1210695 for the reasons set forth in the prior Office Actions and the further reasons below.

CN 1210695 expressly discloses water which is mineralized with calcium glutarate for drinking falling within the scope of applicant's claims (Abstract).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978); *Ex parte Novitski*, 26 USPQ2d 1389, 1390-91 (Bd -Pat. App. & Inter. 1993).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Applicant argues that there is only a possibility that consumed amounts could provide therapeutic doses and that the claimed composition comprises a single dose. Applicant further

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argues that the reference does not necessarily exclude compositions with non-glutarate calcium salts in amounts sufficient to neutralize gastric acidity. However, the rejected claims do not indicate what would be a therapeutic dose, a single dose or an amount of non-glutarate calcium salt which would be sufficient to neutralize gastric acidity. The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 43 USPQ2d 1362 (Fed. Cir. 1997). As such, Applicant has not provided evidence that there is only a possibility that consumed amounts could provide therapeutic doses, that the cited reference does not inherently or expressly disclose single doses, or that the reference does not necessarily exclude compositions with non-glutarate calcium salts in amounts sufficient to neutralize gastric acidity. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 195 USPQ 430, 433 (CCPA 1977).

The rejected claims are not method claims, as such, Applicant's argument relative to methods of inhibiting phosphorous absorption in the GI tract does not overcome the rejection. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Further as indicated above the claims do not define how much or what volume is contained in a single dose. Therefore, Applicant has

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not shown that the prior art reference said limitation is not disclosed, inherently or expressly, in the cited reference.

***Conclusion***

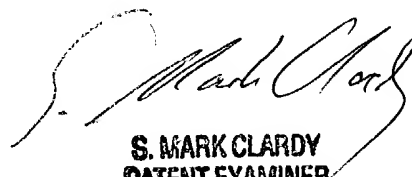
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

FIC

September 17, 2004



**S. MARK CLARDY  
PATENT EXAMINER  
GROUP 1200**  
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